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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,748	04/02/2004	William L. Bunnelle	14369.6US01	1148
23552	7590	08/02/2006	EXAMINER	
MERCHANT & GOULD PC			BOYKIN, TERRESSA M	
P.O. BOX 2903			ART UNIT	
MINNEAPOLIS, MN 55402-0903			PAPER NUMBER	

1711

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/816,748

Applicant(s)

BUNNELLE, WILLIAM L.

Examiner

Terressa M. Boykin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-27 are rejected under 35 U.S.C. 102( b ) as being anticipated by US 6071539 see cols. 1-6, example 1, 2 and 3, and table 1.**

**US 6071539** discloses an effervescent dosage form which incorporates microparticles which are susceptible to rupture upon chewing or which are adapted to provide substantially immediate release of the pharmaceutical ingredients contained in the microparticles. The microparticles comprise a drug encapsulated in a protective material. The microparticles are then mixed with an effervescent agent and then the mixture compressed into tablets.

The effervescent granules have a variety of uses including dental compositions containing enzymes, contact lens etc.

The effervescent granules of this invention can be in the state of powder or fine particles to increase the dissolution rate, and preferably a particle size such that 90% or more passes a 16 mesh (1,000.mu.) screen, and more preferably a particle size such that more than 90% passes a 18 mesh (850 mu m) screen. Generally, the larger the effervescent granule, the longer it will take to completely disintegrate. This is particularly true when there are low levels of effervescent couple present in the granules.

An acidic agent which is in solid state at room temperatures and shows pH 4.5 or lower when saturated into water at room temperatures or its acid alkali metal salts (e.g. sodium salt, potassium salt, etc.) can be employed.

An acidic agent and a carbon dioxide precursor are used respectively in a powdery or granular state, usually 90% or more of them being capable of passing through a 100 mesh (150.mu.) screen. The particle size of the binder used will usually be about 100 mesh (150.mu.). In any case, it is generally acceptable that the additional amount of either component can remain unreacted.

The rate of effervescence can also be controlled by varying the hydrophilicity or hydrophobicity of the hot-melt extrudable binder. Generally, the more hydrophobic the binder, the slower the rate of effervescence. The solubility and rate of dissolution of a

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hydrophobic binder are important factors to consider as the level of binder in the effervescent granule is increased. For example, one can prepare an effervescent granule having a rapid rate of effervescence by a water soluble hot-melt extrudable binder such as an electrolyte or nonelectrolyte such as xylitol, which can form a eutectic mixture with an appropriate acidic agent during hot-melt extrusion.

Conversely, one can prepare an effervescent granule having a slow rate of effervescence by employing a poorly water soluble hot-melt extrudable binder such as hydrogenated castor oil, lipids, wax, cholesterol, fatty acids or mono-, di- or triglycerides. Additionally, an effervescent granule having an intermediate rate of effervescence can be prepared by employing a binder, or combination of binders, such as those just discussed and optionally a surface active agent or cosolvent that improves wetting or disintegration of the effervescent granule.

Plasticizers useful in the reference include low molecular weight polymers, oligomers, copolymers, oils, small organic molecules, low molecular weight polyols having aliphatic hydroxyls, ester-type plasticizers, glycol ethers, poly(propylene glycol), multi-block polymers, single block polymers, low molecular weight poly(ethylene glycol), citrate ester-type plasticizers, triacetin, propylene glycol and glycerin.

Thus, the reference discloses a composition which may be used for contact lenses prepared as claimed by applicants. Since the disclosed parameters, i.e. amounts, are expressed differently and thus may be distinct from those claimed, it is incumbent upon applicant(s) to establish that they are in fact different and whether such difference is unobvious. In view of the above, there appears to be no significant difference between the reference and that which is claimed by applicant(s). Any differences not specifically mentioned appear to be conventional. Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

### **Correspondence**

Please note that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial

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**sources. Applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Terressa Boykin whose telephone number is 571 272-1069. The examiner can normally be reached on Monday through Friday from 6:30am to 3:00pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. The general information number for listings of personnel is ( 571-272-1700).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tmb

  
Examiner Terressa Boykin

**TERRESSA M. BOYKIN  
PRIMARY EXAMINER**